

RECEIVED

SEP 28 2001

TECH CENTER 1600/2900

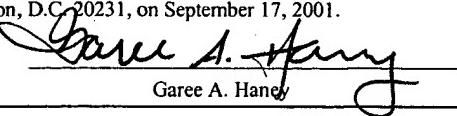
PATENT

Docket No. 204372000901



CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Assistant Commissioner for Patents, Washington, D.C. 20231, on September 17, 2001.


Garee A. Haney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Lynn E. SPITLER et al.

Serial No.: 09/764,546

Filing Date: January 17, 2001

For: THERAPEUTIC PROPERTIES OF
LIPOSOME-ENCAPSULATED
IMMUNOMODULATORS

Examiner: To Be Assigned

Group Art Unit: 1642

INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents Nos. 4, 9, 30, 31, 42, 58 and 92, are included herewith. Copies of all other documents were previously submitted in an Information Disclosure Statement and/or Office Action, directed to the related application Serial Number 09/226,075, filed January 6, 1999, now abandoned, and, accordingly, copies are not included herewith. This protocol conforms with 37 C.F.R. § 1.98(d) and M.P.E.P. 609(A)(2).

The Examiner is requested to make these documents of record in the application.

The documents Nos. 4, 9, 30, 31, 42 and 58, listed on the attached Form PTO-1449 were cited in a Search Report (copy attached) directed to a counterpart international or foreign application.

This Information Disclosure Statement is submitted:

- With the application; accordingly, no fee or separate requirements are required.
- Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
- After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - A fee is required. A check in the amount of * is enclosed.
 - A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly; no fee is believed to be due.
- After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee. Accordingly, a Petition requesting consideration of the Information Disclosure Statement, an authorization to charge our deposit account, and a Certification under 37 C.F.R. § 1.97(e) are provided herein.

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 is to the best of my knowledge and is not to be construed as a representation

that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing 204372000901. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: September 17, 2001

Respectfully submitted,

By:

Kate H. Murashige
Kate H. Murashige
Registration No. 29,959

Morrison & Foerster LLP
3811 Valley Centre Drive
Suite 500
San Diego, California 92130-2332
Telephone: (858) 720-5112
Facsimile: (858) 720-5125



Please type a plus sign (+) inside this box →

RECEIVED

SEP 28 2001

642
#5
Mw

TECH CENTER 1600/2900

PTO/SB/21 (08-00)

Approved for use through 10/31/02. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number Of Pages In This Submission

11

Application Number

09/764,546

Filing Date

January 17, 2001

First Named Inventor

Lynn E. SPITLER et al.

Group Art Unit

1642

Examiner Name

To Be Assigned

Attorney Docket No.

204372000901

ENCLOSURES (check all that apply)

- | | | |
|--|---|---|
| <input type="checkbox"/> Fee Transmittal Form | <input type="checkbox"/> Assignment Papers
(for an Application) | <input type="checkbox"/> After Allowance Communication to Group |
| <input type="checkbox"/> Fee Attached | <input type="checkbox"/> Drawing(s) | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences |
| <input type="checkbox"/> Amendment / Reply | <input type="checkbox"/> Licensing-related Papers | <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) |
| <input type="checkbox"/> After Final | <input type="checkbox"/> Petition | <input type="checkbox"/> Proprietary Information |
| <input type="checkbox"/> Affidavits/declarations | <input type="checkbox"/> Petition to Convert to a Provisional Application | <input type="checkbox"/> Status Letter |
| <input type="checkbox"/> Extension of Time Request | <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return postcard |
| <input type="checkbox"/> Express Abandonment Request | <input type="checkbox"/> Terminal Disclaimer | |
| <input checked="" type="checkbox"/> Information Disclosure Statement; PTO form 1449; copy of International Search Report; and six (6) references | <input type="checkbox"/> Request for Refund | |
| <input type="checkbox"/> Certified Copy of Priority Document(s) | <input type="checkbox"/> CD, Number of CD(s) _____ | |
| <input type="checkbox"/> Response to Missing Parts/ Incomplete Application | | |
| <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | | |

Remarks

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm
or
Individual Name

Kate H. Murashige
Registration No. 29,959

Signature

Kate H. Murashige

Date

September 17, 2001

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on September 17, 2001.

Garee A. Haney
Garee A. Haney

Burden Hours Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>		Docket Number 204372000901	Application Number 09/764,546
		Applicant: Lynn E. Spitler <i>et al.</i>	
		Filing Date January 17, 20001	Group Art Unit 1642
		Mailing Date September 17, 2001	

TECH CENTER 1600/2905

SEP 28 2001

RECEIVED

O I P E J C I S
P A T E N T & T R A D E M A R K O F F I C E
S E P 2 5 2 0 0 1

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	08/30/94	5,342,977	Baschang <i>et al.</i>			
	2.	03/05/96	5,496,804	Reed <i>et al.</i>			
	3.	10/15/96	5,565,478	Kohn <i>et al.</i>			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	4.	06/23/93	EP 0 548 024 A	Europe			

OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	5.	Arbibe, L., <i>et al.</i> , "Endotoxin Induces Expression Of Type II Phospholipase A2 In Macrophages During Acute Lung Injury In Guinea Pigs," J. IMMUNOL., (1997) 159:391-400
	6.	Arditi, M., <i>et al.</i> , "Lipopolysaccharide Stimulates the Tyrosine Phosphorylation of Mitogen-Activated Protein Kinases p44, p42, and p41 in Vascular Endothelial Cells in a Soluble CD14-Dependent Manner," J. IMMUNOL., (1995) 155:3994-4003
	7.	Armitage, R. J. <i>et al.</i> , "IL-15 Has Stimulatory Activity For The Induction Of B Cell Proliferation And Differentiation," J. IMMUNOL., (1995) 154:483-490
	8.	Asano, T., <i>et al.</i> , "Liposome-Encapsulated MTP-PE: A Novel Biologic Agent for Cancer Therapy," J. IMMUNOTHER., (1993) 14:286-292
	9.	Asao, T., <i>et al.</i> , "Eradication of Hepatic Metastases of Carcinoma H-59 by Combination Chemoimmunotherapy with Liposomal Muramyl Tripeptide, 5-Fluorouracil and Leucovorin," CANCER RESEARCH, (1992) 52:6254-6257
	10.	Bellezzi, J.M., <i>et al.</i> , "LPS-Mediated NF- κ B Activation in Rat Kupffer Cells can be Induced Independently of CD14," AM. J. PHYSIOL., (1996) 270:G966-G961
	11.	Cao, S. <i>et al.</i> , "Interleukin 15 Offers Selective Protection From Irinotecan-Induced Intestinal Toxicity In A Preclinical Animal Model," CANCER RES., (1998) 58:3270-4

EXAMINER: (examiner)	DATE CONSIDERED:
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.	

Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>			Docket Number 204372000901	Application Number 09/764,546																														
			Applicant: Lynn E. Spitler et al.																															
			Filing Date January 17, 20001	Group Art Unit 1642																														
			Mailing Date September 17, 2001																															
<p style="text-align: right;">RECEIVED TECH CENTER 1600/2000 SEP 28 2001</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">12.</td> <td>Cao, S. et al., "Interleukin 15 Protects Against Toxicity And Potentiates Antitumor Activity of Fluorouracil Alone And In Combination With Leucovorin In Rats Bearing Colorectal Cancer," CANCER RES., (1998) 58:1695-9</td> </tr> <tr> <td>13.</td> <td>Carson, W.E., et al., "Interleukin (IL) 15 is a Novel Cytokine that Activates Human Natural Killer Cells via Components of the IL-2 Receptor," J. EXP. MED., (1994) 180:1395-1403</td> </tr> <tr> <td>14.</td> <td>Celada, A., et al., "Role of Protein Kinase C and Intracellular Calcium Mobilization in the Induction of Macrophage Tumoricidal Activity by Interferon-γ," J. IMMUNOL., (1986) 137:2373-2379</td> </tr> <tr> <td>15.</td> <td>Chedid L, et al., "Failure of Endotoxin to Increase Nonspecific Resistance to Infection of Lipopolysaccharide Low-Responder Mice," INFECT. IMMUNOL., (1976) 13(3):722-7</td> </tr> <tr> <td>16.</td> <td>Ciacci, C., et al., "Functional Interleukin-2 Receptors on Intestinal Epithelial Cells," J. CLIN. INVEST., (1993) 92:527-32</td> </tr> <tr> <td>17.</td> <td>Constantinou, A. et al., "Genistein As An Inducer Of Tumor Cell Differentiation: Possible Mechanisms Of Action," PROCEEDINGS OF THE SOCIETY EXPERIMENTAL BIOLOGY AND MEDICINE, (1995) 208(1):109-15</td> </tr> <tr> <td>18.</td> <td>Ding, A. H. et al., "Release Of Reactive Nitrogen Intermediates And Reactive Oxygen Intermediates From Mouse Peritoneal Macrophages," J. IMMUNOL., (1988) 141:2407-12</td> </tr> <tr> <td>19.</td> <td>Ding, A., et al., "Taxol Shares the Ability of Bacterial Lipopolysaccharide to Induce Tyrosine Phosphorylation of Microtubule-Associated Protein Kinase," J. IMMUNOL., (1993) 151(10):5596-5602</td> </tr> <tr> <td>20.</td> <td>Dinney C.P.N., et al. Principles and Practice of Genitourinary Oncology, Philadelphia: Lippincott-Raven, 1996; pp.17-24</td> </tr> <tr> <td>21.</td> <td>Dinney, C. P. N. et al., "Therapy Of Spontaneous Lung Metastasis Of Murine Renal Adenocarcinoma By Systemic Administration Of Liposomes Containing The Macrophage Activator CGP 31362," CANCER RES., (1991) 51:3741-7</td> </tr> <tr> <td>22.</td> <td>Dinney, C.P.N. et al., "Immunotherapy of Murine Renal Adenocarcinoma by Systemic Administration of Liposomes Containing the Synthetic Macrophage Activator CGP 31362 or CGP 19835A in Combination with Interleukin 2 or γ-Interferon," Cancer Res (1992) 52:1155-1161</td> </tr> <tr> <td>23.</td> <td>Doherty, T. M., et al., "Induction And Regulation Of IL-15 Expression In Murine Macrophages," J. IMMUNOL., (1996) 156:735-41</td> </tr> <tr> <td>24.</td> <td>Dong, Z. et al., "Activation Of Tumoricidal Properties In Macrophages By Lipopolysaccharide Requires Protein-Tyrosine Kinase Activity," J. LEUKOCYTE BIOL., (1993) 53:53-60</td> </tr> <tr> <td>25.</td> <td>Dong, Z. et al., "Organ-Specific Modulation Of Steady-State mdr Gene Expression And Drug Resistance In Murine Colon Cancer Cells," J. NATL. CANCER INST., (1994) 86:913-20</td> </tr> <tr> <td>26.</td> <td>Dong, Z. et al., "Protein Tyrosine Kinase Inhibitors Decrease Induction Of Nitric Oxide Synthase Activity In Lipopolysaccharide-Responsive And Lipopolysaccharide-Nonresponsive Murine Macrophages," J. IMMUNOL., (1993) 151:2717-25</td> </tr> </table>					12.	Cao, S. et al., "Interleukin 15 Protects Against Toxicity And Potentiates Antitumor Activity of Fluorouracil Alone And In Combination With Leucovorin In Rats Bearing Colorectal Cancer," CANCER RES., (1998) 58:1695-9	13.	Carson, W.E., et al., "Interleukin (IL) 15 is a Novel Cytokine that Activates Human Natural Killer Cells via Components of the IL-2 Receptor," J. EXP. MED., (1994) 180:1395-1403	14.	Celada, A., et al., "Role of Protein Kinase C and Intracellular Calcium Mobilization in the Induction of Macrophage Tumoricidal Activity by Interferon- γ ," J. IMMUNOL., (1986) 137:2373-2379	15.	Chedid L, et al., "Failure of Endotoxin to Increase Nonspecific Resistance to Infection of Lipopolysaccharide Low-Responder Mice," INFECT. IMMUNOL., (1976) 13(3):722-7	16.	Ciacci, C., et al., "Functional Interleukin-2 Receptors on Intestinal Epithelial Cells," J. CLIN. INVEST., (1993) 92:527-32	17.	Constantinou, A. et al., "Genistein As An Inducer Of Tumor Cell Differentiation: Possible Mechanisms Of Action," PROCEEDINGS OF THE SOCIETY EXPERIMENTAL BIOLOGY AND MEDICINE, (1995) 208(1):109-15	18.	Ding, A. H. et al., "Release Of Reactive Nitrogen Intermediates And Reactive Oxygen Intermediates From Mouse Peritoneal Macrophages," J. IMMUNOL., (1988) 141:2407-12	19.	Ding, A., et al., "Taxol Shares the Ability of Bacterial Lipopolysaccharide to Induce Tyrosine Phosphorylation of Microtubule-Associated Protein Kinase," J. IMMUNOL., (1993) 151(10):5596-5602	20.	Dinney C.P.N., et al. Principles and Practice of Genitourinary Oncology, Philadelphia: Lippincott-Raven, 1996; pp.17-24	21.	Dinney, C. P. N. et al., "Therapy Of Spontaneous Lung Metastasis Of Murine Renal Adenocarcinoma By Systemic Administration Of Liposomes Containing The Macrophage Activator CGP 31362," CANCER RES., (1991) 51:3741-7	22.	Dinney, C.P.N. et al., "Immunotherapy of Murine Renal Adenocarcinoma by Systemic Administration of Liposomes Containing the Synthetic Macrophage Activator CGP 31362 or CGP 19835A in Combination with Interleukin 2 or γ -Interferon," Cancer Res (1992) 52:1155-1161	23.	Doherty, T. M., et al., "Induction And Regulation Of IL-15 Expression In Murine Macrophages," J. IMMUNOL., (1996) 156:735-41	24.	Dong, Z. et al., "Activation Of Tumoricidal Properties In Macrophages By Lipopolysaccharide Requires Protein-Tyrosine Kinase Activity," J. LEUKOCYTE BIOL., (1993) 53:53-60	25.	Dong, Z. et al., "Organ-Specific Modulation Of Steady-State mdr Gene Expression And Drug Resistance In Murine Colon Cancer Cells," J. NATL. CANCER INST., (1994) 86:913-20	26.	Dong, Z. et al., "Protein Tyrosine Kinase Inhibitors Decrease Induction Of Nitric Oxide Synthase Activity In Lipopolysaccharide-Responsive And Lipopolysaccharide-Nonresponsive Murine Macrophages," J. IMMUNOL., (1993) 151:2717-25
12.	Cao, S. et al., "Interleukin 15 Protects Against Toxicity And Potentiates Antitumor Activity of Fluorouracil Alone And In Combination With Leucovorin In Rats Bearing Colorectal Cancer," CANCER RES., (1998) 58:1695-9																																	
13.	Carson, W.E., et al., "Interleukin (IL) 15 is a Novel Cytokine that Activates Human Natural Killer Cells via Components of the IL-2 Receptor," J. EXP. MED., (1994) 180:1395-1403																																	
14.	Celada, A., et al., "Role of Protein Kinase C and Intracellular Calcium Mobilization in the Induction of Macrophage Tumoricidal Activity by Interferon- γ ," J. IMMUNOL., (1986) 137:2373-2379																																	
15.	Chedid L, et al., "Failure of Endotoxin to Increase Nonspecific Resistance to Infection of Lipopolysaccharide Low-Responder Mice," INFECT. IMMUNOL., (1976) 13(3):722-7																																	
16.	Ciacci, C., et al., "Functional Interleukin-2 Receptors on Intestinal Epithelial Cells," J. CLIN. INVEST., (1993) 92:527-32																																	
17.	Constantinou, A. et al., "Genistein As An Inducer Of Tumor Cell Differentiation: Possible Mechanisms Of Action," PROCEEDINGS OF THE SOCIETY EXPERIMENTAL BIOLOGY AND MEDICINE, (1995) 208(1):109-15																																	
18.	Ding, A. H. et al., "Release Of Reactive Nitrogen Intermediates And Reactive Oxygen Intermediates From Mouse Peritoneal Macrophages," J. IMMUNOL., (1988) 141:2407-12																																	
19.	Ding, A., et al., "Taxol Shares the Ability of Bacterial Lipopolysaccharide to Induce Tyrosine Phosphorylation of Microtubule-Associated Protein Kinase," J. IMMUNOL., (1993) 151(10):5596-5602																																	
20.	Dinney C.P.N., et al. Principles and Practice of Genitourinary Oncology, Philadelphia: Lippincott-Raven, 1996; pp.17-24																																	
21.	Dinney, C. P. N. et al., "Therapy Of Spontaneous Lung Metastasis Of Murine Renal Adenocarcinoma By Systemic Administration Of Liposomes Containing The Macrophage Activator CGP 31362," CANCER RES., (1991) 51:3741-7																																	
22.	Dinney, C.P.N. et al., "Immunotherapy of Murine Renal Adenocarcinoma by Systemic Administration of Liposomes Containing the Synthetic Macrophage Activator CGP 31362 or CGP 19835A in Combination with Interleukin 2 or γ -Interferon," Cancer Res (1992) 52:1155-1161																																	
23.	Doherty, T. M., et al., "Induction And Regulation Of IL-15 Expression In Murine Macrophages," J. IMMUNOL., (1996) 156:735-41																																	
24.	Dong, Z. et al., "Activation Of Tumoricidal Properties In Macrophages By Lipopolysaccharide Requires Protein-Tyrosine Kinase Activity," J. LEUKOCYTE BIOL., (1993) 53:53-60																																	
25.	Dong, Z. et al., "Organ-Specific Modulation Of Steady-State mdr Gene Expression And Drug Resistance In Murine Colon Cancer Cells," J. NATL. CANCER INST., (1994) 86:913-20																																	
26.	Dong, Z. et al., "Protein Tyrosine Kinase Inhibitors Decrease Induction Of Nitric Oxide Synthase Activity In Lipopolysaccharide-Responsive And Lipopolysaccharide-Nonresponsive Murine Macrophages," J. IMMUNOL., (1993) 151:2717-25																																	
EXAMINER:		DATE CONSIDERED:																																
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.																																		

Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)		Docket Number 204372000901	Application Number 09/764,546
		Applicant: Lynn E. Spitler <i>et al.</i>	
		Filing Date January 17, 20001	Group Art Unit 1642
SEP 25 2001		Mailing Date September 17, 2001	

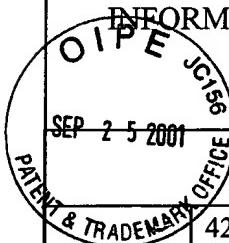
27.	Dong, Z. <i>et al.</i> , "Tyrosine Phosphorylation Of Mitogen-Activated Protein Kinases Is Necessary For Activation Of Murine Macrophages By Natural And Synthetic Bacterial Products," J. EXP. MED., (1993) 177:1071-7
28.	Dong, Z., <i>et al.</i> , "Activation of Inducible Nitric Oxide Synthase Gene in Murine Macrophages Requires Protein Phophatases 1 and 2A Activities," J. LEUKOC. BIOL., (1993) 58:725-32
29.	Dudley, D. T., <i>et al.</i> , "A Synthetic Inhibitor Of The Mitogen-Activated Protein Kinase Cascade," PROC. NATL. ACAD. SCI. USA (1995) 92:7686-9
30.	Dzierzbicka, K., <i>et al.</i> , POSTEPY HIGIENY I MEDYCINY DOSWIADCZALNEJ, (1997) 51(2):227-236
31.	Eue, I., <i>et al.</i> , "Induction of Nitric Oxide Production and Tumoricidal Properties in Murine Macrophages by a New Synthetic Lipopeptide JBT3020 Encapsulated in Liposomes," JOURNAL OF IMMUNOTHERAPY, (1998) 21(5):340-351
32.	Fidler, I. J. <i>et al.</i> , "Eradication Of Spontaneous Metastases And Activation Of Alveolar Macrophages By Intravenous Injection Of Liposomes Containing Muramyl Dipeptide," PROC. NATL. ACAD. SCI. USA, (1981) 78(3):1680-4
33.	Fidler, I. J., "Optimization And Limitations Of Systemic Treatment Of Murine Melanoma Metastases With Liposomes Containing Muramyl Tripeptide Phosphatidylethanolamine," CANCER IMMUNOL. IMMUNOTHER., (1986) 21:169-73
34.	Fidler, I. J., "Targeting Of Immunomodulators To Mononuclear Phagocytes For Therapy Of Cancer," ADV. DRUG DEL. REV., (1988) 2:69-106
35.	Fidler, I. J., <i>et al.</i> , "Mechanisms of Macrophage-Mediated Tumor Cell Lysis: Role for the Monokines Tumor Necrosis Factor and Interleukin," PROG. CLIN. BIOL. RES., (1989) 288:169-181
36.	Fidler, I.J., "Macrophages and Metastasis -- A Biological Approach to Cancer Therapy: Presidential Address," CANCER RES., (1985) 45:4714-26
37.	Fidler, I.J., "Therapy of Cancer Metastasis by Systemic Activation of Macrophages," ADV. PHARMACOL., (1994) 30:271-326
38.	Fidler, I.J., <i>et al.</i> , "Differential Release of TNF- α , IL 1, and PGE ₂ by Human Blood Monocytes Subsequent to Interaction with Different Bacterial Derived Agents," LYMPHOKINE RES., (1990) 9(4):449-63
39.	Findik, D. <i>et al.</i> , "Protein Kinase A Inhibitors Enhance Radiation-Induced Apoptosis," J. CELL BIOCHEM., (1995) 57:12-21
40.	Gallay, P., <i>et al.</i> , "Short Term Exposure to Lipopolysaccharide is Sufficient to Activate Human Monocytes," J. IMMUNOL., (1993) 150(11):5086-5093
41.	Giri, J.G., <i>et al.</i> , "Utilization of the β and γ Chains of the IL-2 Receptor by the Novel Cytokine IL-15," EMBO. J., (1994) 13(12):2822-30

RECEIVED

SEP 28 2001

EXAMINER:	DATE CONSIDERED:
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.	

Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)		Docket Number 204372000901	Application Number 09/764,546
		Applicant: Lynn E. Spitler <i>et al.</i>	
		Filing Date January 17, 20001	Group Art Unit 1642
		Mailing Date September 17, 2001	



42.	Goldbach, P., <i>et al.</i> , "In Situ Activation of Mouse Alveolar Macrophages by Aerosolized Liposomal IFN-Gamma and Muramyl Tripeptide," AM. J. PHYSIOLOGY, (1996) 270(3):1429-1434
43.	Grabstein, K. H. <i>et al.</i> , "Cloning Of A T Cell Growth Factor That Interacts With The β Chain Of The Interleukin-2 Receptor," SCIENCE, (1994) 264:965-8
44.	Hambleton, J., <i>et al.</i> , "Activation of c-Jun N-terminal Kinase in Bacterial Lipopolysaccharide-Stimulated Macrophages," PROC. NATL. ACAD. SCI. USA, (1996) 93:2774-8
45.	Hambleton, J., <i>et al.</i> , "Activation of Raf-1 and Mitogen-Activated Protein Kinase in Murine Macrophages Partially Mimics Lipopolysaccharide-Induced Signaling Events," J. EXP. MED., (1995) 182:147-154
46.	Han, J., <i>et al.</i> , "A MAP Kinase Targeted by Endotoxin and Hyperosmolarity in Mammalian Cells," SCIENCE, (1994) 265:808-11
47.	Ichinose, Y., <i>et al.</i> , "Destruction of Tumor Cells by Monokines Released from Activated Human Blood Monocytes: Evidence for Parallel and Additive Effects of IL-1 and TNF," CANCER IMMUNOL. IMMUNOTHER., (1988) 27:7-12
48.	Ikuno, N. <i>et al.</i> , Irinotecan(CPT-11) And Characteristic Mucosal Changes In The Mouse Ileum And Cecum," JOURNAL OF THE NATIONAL CANCER INSTITUTE, (1995) 87(24):1876-83
49.	Jarvis, W. D. <i>et al.</i> , Induction Of Apoptotic DNA Fragmentation And Cell Death in HL-60 Human Promyelocytic Leukemia Cells By Pharmacological Inhibitors Of Protein Kinase C," CANCER RES., (1994) 54:1707-14
50.	Jonjic, N., <i>et al.</i> , "Heterogeneous Susceptibility of Human Melanoma Clones to Monocyte Cytotoxicity: Role of ICAM-1 Defined by Antibody Blocking and Gene Transfer," EUR. J. IMMUNOL., (1992) 22:2255-60
51.	Killion, J. J. <i>et al.</i> , "Maintenance Of Intestinal Epithelium Structural Integrity And Mucosal Leukocytes During Chemotherapy By Oral Administration Of Muramyl Tripeptide Phosphatidylethanolamine," CANCER BIOTHERAPY AND RADIOPHARMACEUTICALS (1996) 11(6):363-71
52.	Killion, J. J. <i>et al.</i> , "Prevention Of Chemotherapy- Or X-Irradiation-induced Monocytopenia By Oral Administration Of Lipophilic Muramyl Tripeptide," ONCOLOGY RESEARCH, (1994) 6(3):357-64
53.	Killion, J. J. <i>et al.</i> , "Sequential Therapy With Chemotherapeutic Drugs And Liposome-Encapsulated Muramyl Tripeptide: Determination Of Potential Interactions Between These Agents, ONCOLOGY RESEARCH, (1992) 4(10):413-8
54.	Killion, J. J. <i>et al.</i> , "Systemic Targeting Of Liposome-Encapsulated Immunomodulators To Macrophages For Treatment Of Cancer Metastasis," IMMUNOMETHODS, (1994) 4:273-9
55.	Kleinerman, E. S. <i>et al.</i> , "Activation Of Tumoricidal Properties In Monocytes from Cancer Patients Following Intravenous Administration Of Liposomes Containing Muramyl Tripeptide Phosphatidylethanolamine," CANCER RES., (1989) 49:4665-70

RECEIVED

SEP 28 2001

EXAMINER:	DATE CONSIDERED:
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.	

<p>Form PTO-1449</p> <p>O I P E J C 156</p> <p>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</p> <p><i>(Use several sheets if necessary)</i></p> <p>SEP 25 2001 USPTO OFFICE</p>	Docket Number 204372000901	Application Number 09/764,546
	Applicant:	
	Lynn E. Spitzer <i>et al.</i>	
	Filing Date January 17, 20001	Group Art Unit 1642
Mailing Date September 17, 2001		

- | | | |
|-------------|-----|---|
| & TRADEMARK | 56. | Kleinerman, E. S. et al., "Phase II Study Of Liposomal Muramyl Tripeptide In Osteosarcoma: The Cytokine Cascade And Monocyte Activation Following Administration," J. CLIN. ONCOL., (1992) 10(8):1310-16 |
| | 57. | Kleinerman, E. S. et al., "Unique Histological Changes In Lung Metastases Of Osteosarcoma Patients Following Therapy With Liposomal Muramyl Tripeptide (CGP 19835A Lipid), CANCER IMMUNOL. IMMUNOTHER., (1992) 34:211-20 |
| | 58. | Kleinerman, E. S. et al., "Combination Therapy with Ifosfamide and Liposome-Encapsulated Muramyl Tripeptide: Tolerability, Toxicity and Immune Stimulation," JOURNAL OF IMMUNOTHERAPY, (1995) 17(3):181-193 |
| | 59. | Kozlowski, J.M., et al., "A Human Melanoma Line Heterogeneous with Respect to Metastatic Capacity in Athymic Nude Mice," J. NATL. CANCER INST., (1984) 72(4):913-7 |
| | 60. | Kumar, R. et al., "Differential Regulation Of Metalloelastase Activity In Murine Peritoneal Macrophages By Granulocyte-Macrophage Colony-Stimulating Factor And Macrophage Colony-Stimulating Factor, J. IMMUNOL., (1996) 157:5104-11 |
| | 61. | Liu, M.K., et al., "CD14-Dependent Activation of Protein Kinase C and Mitogen-Activated Protein Kinases (p42 and p44) in Human Monocytes Treated with Bacterial Lipopolysaccharide," J. IMMUNOL., (1994) 153:2642-2652 |
| | 62. | MacEwen, E. G. et al., "Therapy For Osteosarcoma in Dogs With Intravenous Injection Of Liposome-Encapsulated Muramyl Tripeptide," JOURNAL OF THE NATIONAL CANCER INSTITUTE, (1989) 81(12):935-8 |
| | 63. | MacMicking, J. D. et al., "Altered Responses To Bacterial Infection And Endotoxic Shock in Mice Lacking Inducible Nitric Oxide Synthase," CELL, (1995) 81:641-50 |
| | 64. | Manthey, C. L. et al., "Taxol Increases Steady-State Levels Of Lipopolysaccharide-Inducible Genes And Protein-Tyrosine Phosphorylation In Murine Macrophages," J. IMMUNOL., (1992) 149(7):2459-65 |
| | 65. | Meisel, C. et al., "Differential Regulation Of Monocytic Tumor Necrosis Factor- α And Interleukin-10 Expression, EUR. J. IMMUNOL., (1996) 26:1580-6 |
| | 66. | Murray, J. L. et al., "Phase I Trial Of Liposomal Muramyl Tripeptide Phosphatidylethanolamine In Cancer Patients," J. CLIN. ONCOL., (1989) 7(12):1915-1925 |
| | 67. | Nathan, C.F., "Secretory Products of Macrophages," J. CLIN. INVEST., (1987) 79:319-26 |
| | 68. | Niewoehner, D.E., et al., "Injurious Effects of Lysophosphatidylcholine on Barrier Properties of Alveolar Epithelium," J. APPL. PHYSIOL., (1987) 63(5):1979-86 |
| | 69. | Nii, A. et al., "Optimization Of The Liposomes Encapsulating A New Lipopeptide CGP 31362 For Efficient Activation Of Tumoricidal Properties In Monocytes And Macrophages, J. IMMUNOTHER., (1991) 10:236-46 |

RECEIVED

SEP 28 2001

EXAMINER: _____ **DATE CONSIDERED:** _____
TECH CENTER 1600/2900

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449 OPTIONAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>		Docket Number 204372000901	Application Number 09/764,546
		Applicant: Lynn E. Spitler et al.	
		Filing Date January 17, 20001	Group Art Unit 1642
		Mailing Date September 17, 2001	

70.	Nii, A., et al., "The Incubation of Human Blood Monocytes with Tumor Necrosis Factor- α Leads to Lysis of Tumor Necrosis Factor -Sensitive but Not Resistant Tumor Cells," LYMPHOKINE RES., (1990) 9(2):113-24
71.	Novotney, M., et al., "Protein Kinase C in Tumoricidal Activation of Mouse Macrophage Cell Lines," BIOCHEMISTRY, (1991) 30:5597-5604
72.	Paul, A., et al., "Protein Kinase C and Tyrosine Kinase Pathways Regulate Lipopolysaccharide-Induced Nitric Oxide Synthase Activity in RAW 264.7 Murine Macrophages," BR. J. PHARMACOL., (1995) 114:482-8
73.	Reinecker, H-C. et al., "Human Intestinal Epithelial Cells Express Functional Cytokine Receptors Sharing The Common γc Chain Of The Interleukin 2 Receptor," PROC. NATL. ACAD. SCI. USA, (1995) 92:8353-7
74.	Reinecker, H-C. et al., "Intestinal Epithelial Cells Both Express And Respond to Interleukin 15," GASTROENTEROLOGY, (1996) 111:1706-13
75.	Saiki, I., et al., "Synergistic Activation by Recombinant Mouse Interferon- γ and Muramyl Dipeptide of Tumoricidal Properties in Mouse Macrophages," J. IMMUNOL., (1985) 135(1):684-8
76.	Sanghera, J. S. et al., "Activation Of Multiple Proline-Directed Kinases By Bacterial Lipopolysaccharide In Murine Macrophages, J. IMMUNOL., (1996) 156:4457-65
77.	Schroit, A. J. et al., "Effects Of Liposome Structure And Lipid Composition On The Activation Of The Tumoricidal Properties Of Macrophages By Liposomes Containing Muramyl Dipeptide," CANCER RES., (1982) 42:161-7
78.	Schumann, R.R., et al., "Structure and Function of Lipopolysaccharide Binding Protein," SCIENCE (1990) 249:1429-1431
79.	Shinji, H., et al., "LPS Induces Selective Translocation of Protein Kinase C- β in LPS-Responsive Mouse Macrophages, but Not in LPS-Nonresponsive Mouse Macrophages," J. IMMUNOL., (1994) 153:5760-5771
80.	\checkmark Stefanová, I., et al., "GPI-Anchored Cell-Surface Molecules Complexed to Protein Tyrosine Kinases," SCIENCE, (1991) 254:1016-9
81.	\checkmark Stefanová, I., et al., "Lipopolysaccharide Induces Activation of CD14-Associated Protein Tyrosine Kinase p53/56 ^{dyn} ," J. BIOL. CHEM., (1993) 268:20725-9
82.	Sweet, M. J., et al., "Endotoxin Signal Transduction in Macrophages," J. LEUKOC. BIOL., (1996) 60:8-26
83.	Talmadge, J.E., et al., "Cancer Metastasis is Selective or Random Depending on the Parent Tumour Population," NATURE, (1982) 297:593-4
84.	Utsugi, T., et al., "Comparative Efficacy of Liposomes Containing Synthetic Bacterial Cell Wall Analogues for Tumoricidal Activation of Monocytes and Macrophages," CANC. IMMUNOTHER., (1991) 33:285-92

RECEIVED

EXAMINER:	DATE CONSIDERED:
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.	

Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>			Docket Number 204372000901	Application Number 09/764,546
			Applicant: Lynn E. Spitler et al.	
			Filing Date January 17, 20001	Group Art Unit 1642
			Mailing Date September 17, 2001	

O I P E SEP 25 2001 PATENT & TRADEMARK OFFICE	85.	Utsugi, T., et al., "In Situ Activation of Mouse Macrophages and Therapy of Spontaneous Renal Cell Cancer Metastasis by Liposomes Containing the Lipopeptide CGP 31362," CANC. IMMUNOL. IMMUNOTHER., (1991) 33:375-381		
	86.	Van Hoogeveest P, et al. <i>Liposomes in the therapy of infectious diseases and cancer</i> . Liss, New York, 1989; pp. 453-466		
	87.	Watson, J., et al., "The Genetic Mapping of a Defective LPS Response Gene in C3H/HeJ Mice," J. IMMUNOL., (1978) 120:422-5		
	88.	Weinstein, S. L. et al., "Lipopolysaccharide-Induced Protein Tyrosine Phosphorylation In Human Macrophages Is Mediated By CD14," J. IMMUNOL., (1993) 151:3829-38		
	89.	Weinstein, S.L., et al., "Bacterial Lipopolysaccharide Induces Tyrosine Phosphorylation and Activation of Mitogen-Activated Protein Kinases in Macrophages," J. BIOL CHEM (1992) 267(21):14955-62		
	90.	Weinstein, S.L., et al., "Bacterial Lipopolysaccharide Stimulates Protein Tyrosine Phosphorylation in Macrophages," PROC NATL ACAD SCI USA, (1991) 88:4148-52		
	91.	Wright, S.D., et al., "CD14, a Receptor for Complexes of Lipopolysaccharide (LPS) and LPS Binding Protein," SCIENCE, (1990) 249:1431-2		
	92.	Xie, K. et al., "Direct Correlation Between Expression Of Endogenous Inducible Nitric Oxide Synthase And Regression Of M5076 Reticulum Cell Sarcoma Hepatic Metastases In Mice Treated With Liposomes Containing Lipopeptide CGP 31362," CANCER RES., (1995) 55:3123-31		
	93.	Xie, K. et al., "Transfection With The Inducible Nitric Oxide Synthase Gene Suppresses Tumorigenicity And Abrogates Metastasis by K-1735 Murine Melanoma Cells," J. EXP. MED., (1995) 181:1333-43		

RECEIVED
SEP 28 2001
TECH CENTER 1600/2900

EXAMINER:	DATE CONSIDERED:
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.	